STRADLING YOCCA CARLSON & RAUTH
A PROFESSIONAL CORPORATION
ATTORNEYS AT LAW
660 NEWPORT CENTER DRIVE, SUITE 1600
NEWPORT BEACH, CA 92660-6422
TELEPHONE (949) 725-4000
FACSIMILE (949) 725-4100

SAN FRANCISCO OFFICE
44 MONTGOMERY STREET, SUITE 4200
SAN FRANCISCO, CALIFORNIA 94104
TELEPHONE (415) 283-2240
FACSIMILE (415) 283-2255

SANTA BARBARA OFFICE
302 OLIVE STREET
SANTA BARBARA, CALIFORNIA 93101
TELEPHONE (805) 564-0065
FACSIMILE (805) 564-1044

LOUIS C. CULLMAN
DIRECT DIAL: (949) 725-4154
LCULLMAN@SYCR.COM

CERTIFICATE OF EXPRESS MAIL

I hereby certify that on November 26, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage in an envelope addressed to: Mail Stop: Patent Term Extension, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. § 1.8(a)
☐with sufficient postage as first class mail

37 C.F.R. § 1.10
☒as "Express Mail Post Office to Addressee" Mailing Label No.

EV 308811878 US

Shauna Murray

APPLICATION FOR PATENT TERM EXTENSION UNDER 35 U.S.C. § 156

Mail Stop: Patent Term Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

RE: Application for Patent Term Extension Pursuant to 35 U.S.C. § 156 (37 C.F.R. §1.740) United States Patent Number 6,309,402

Dear Commissioner:

Enclosed is an application for patent term extension pursuant to 37 C.F.R. §1.740. The owner (assignee) of record, Medtronic Vascular (formerly Medtronic AVE) is submitting this application. All rights in United States Patent Number (USPN) 6,309,402 are held by and vested in Medtronic Vascular a Delaware Corporation and a wholly owned subsidiary of Medtronic, Inc., a Delaware company. Medtronic Vascular's corporate headquarters are located at 3576 Unocal Place, Santa Rosa, CA 95403. A brief chain of title summary follows.

Brad Jendersee, Robert Lashinski and Michael Bonneau are the named inventors of USPN 6,309,402 (USPASN 09/189,597) which is a continuation of USPN 5,836,965 (UNPASN 08/478,192) which is a continuation-in-part of United States Patent Application Serial Number (USPASN) 08/326,023 filed October 19, 1994, now abandoned. Jendersee, Lashinski and Bonneau assigned their entire right, title and interest in USPASN 08/478,192), together with all divisions and

continuations to Applied Vascular Engineering and its successors and assigns on July 20, 1995. This assignment was recorded in the records of the United States Patent and Trademark Office on Reel 7689, Frame 0104. Applied Vascular Engineering then assigned its entire rights, title and interests to Arterial Vascular Engineering, and its successors and assigns. This assignment was recorded in the records of the United States Patent and Trademark Office on Reel 786389, Frame 0672.

On January 30th, 1996 Applied Vascular Engineering, Inc. changed its name to Arterial Vascular Engineering, Inc. Applied Vascular Engineering then assigned its entire right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part to Arterial Vascular Engineering. This assignment was executed January 30th, 1996 and was recorded March 20, 1996. A complete microfilm copy is available in the USPTO records on reel 8522, frame 0049.

Medtronic, Inc. acquired the assets of Arterial Vascular Engineering (AVE) through acquisition on January 29th, 1999 and formed a new Delaware Corporation named Medtronic AVE. Arterial Vascular Engineering assigned its entire right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part to Medtronic AVE. This assignment was executed January 28th, 1999 and was recorded January 31, 1999. A complete microfilm copy is available in the USPTO records on reel 011258, frame 0053.

Subsequently, Medtronic AVE changed its name to Medtronic Vascular, the present applicant, wherein all right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part now reside. Therefore, the application for patent term extension, Medtronic Vascular, is the owner of all rights title and interests in USPN 6,309,402, the subject patent of the present patent term extension application.

Documents supporting the above title chain for USPN 6,309,402 can be found in Appendix A of this application for patent term extension.

1) Complete Identification of the Approved Product by appropriate chemical and generic name, physical structure or characteristics:

The approved product is an over-the-wire coronary stent system for use in patients with symptomatic ischemic heart disease due to discrete single de novo and restenotic lesions. The FDA product code is MAF for Stents, Coronary. The Medtronic Vascular stent marketed as the "S8 Over-the-Wire System" or alternatively under the trademarked name "Driver Stent Delivery System." The System includes a cobalt-based modular stent mounted on a balloon catheter as depicted in Figure 1 below[1]. Figure 2 A and B[2] depict the approved the S8 stent delivery system with the stent crowns securely encapsulated by balloon material.

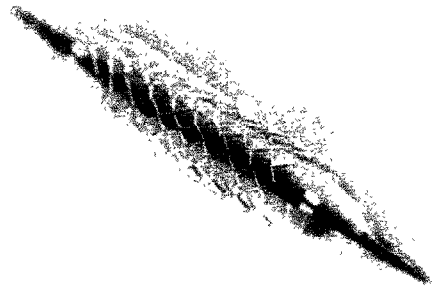


Figure 1

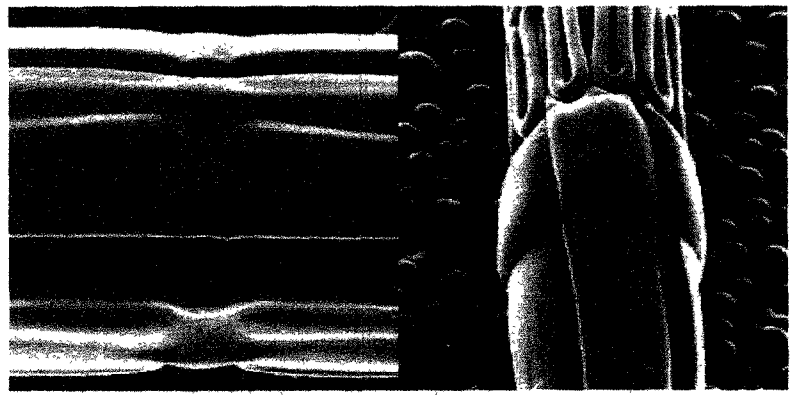


Figure 2 A and B

[1] See http://www.medtronic.com/medtronic_vascular/cs_drivermx.html
[2] *Id*

2) A complete identification of the Federal statue including the applicable provision of law under which the regulatory review occurred:

The Federal Statue under which regulatory review took place for the Medtronic Vascular's S8 Over-the-Wire System is 37 C.F.R. §814.

3) The date on which the product received permission for commercial marketing or use under the provision of law which the applicable regulatory review period occurred.

The Medtronic Vascular S8 Over-the-Wire System was approved for marketing October 1, 2003.

4) Statement that the present application is being submitted within the sixty day period permitted for submission and an identification of the date of the last day on which the application could be submitted.

The present application for patent term extension is being submitted with the sixty day period permitted for submission pursuant to 37 C.F.R. §1.720(f). The last day for submission of the present application is November 30, 2003. However, because November 30, 2003 is a Sunday, this application may be mailed December 1, 2003.

5) The complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue and the expiration date.

The present application for extension is for United States Patent Number 6,309,402 issued October 30, 2001 and expiring December 19, 2014. The inventors are Brad Jendersee, Robert Lashinski, and Michael Bonneau.

6) A copy of the entire patent for which extension is being sought, including the entire specification, claims and drawing.

A copy of U.S. patent number 6,309,402 is attached as Appendix B.

7) A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent.

There are no disclaimers, certificates of correction or reexamination certificates issued on U.S. patent number 6,309,402. A copy of the maintenance fee payment record is provided as Appendix C.

8) Statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which at least one such patent claims reads on the approved product.

United States patent number 6,309,402 claims the S8 Over-the-Wire Coronary Stent System approved October 1, 2003 and a method of making the approved S8 stent. The applicant asserts that claims 1-19 read on the approved device and that claims 20-36 on the method of making the approved device.

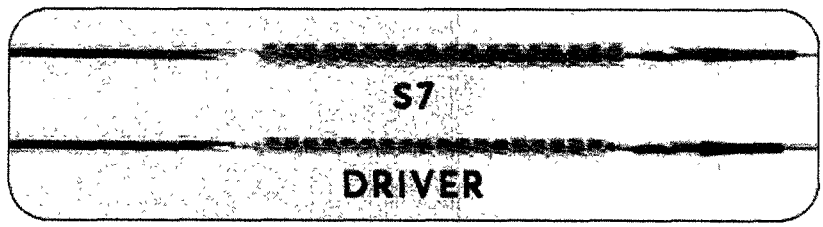
In particular, claim 1 reads on the approved device as follows:

Claim Chart Comparing Claim 1 of U.S. Patent 6,309,402 element-by-element with the S8 Over-the-Wire Coronary Stent

Claim 1 of U.S. Patent 6,309,402	**Corresponding Features of the S8 Over-the-Wire Coronary Stent System**
1. A stent delivery system comprising:	The S8 Over-the-Wire Coronary Stent System is intended for implantation in a vessel within the human body. Therefore, the approved device is a stent delivery system.
a balloon catheter having a catheter body, a balloon positioned upon said catheter body and a portion defining an inflation lumen for selectively inflating and deflating said balloon;	Figures 1 and Figure 3 clearly show the approved S8 stent mounted on the balloon of a balloon catheter. The catheter having a body, a balloon (see the inflated balloon in Figure 1 of this application). The catheter having a central lumen as depicted in Figure 5 of this application below. The lumen allows for "selectively inflating and deflating" in accordance with the teachings inherent in the art of balloon catheters-based stent delivery.
a stent having a generally cylindrical shape and a first diameter for intraluminal delivery, said stent being expandable to a second diameter for deployment in a vessel;	Figure 5 below clearly shows the approved device's first diameter prior to intraluminal delivery. Figure 1 depicts the approved device's second expanded diameter. Note also Figure 4 wherein the stent is fully deployed in a vessel.
wherein said stent is mounted on said balloon of said balloon catheter for implantation in a vessel within the human body, said stent retained in indentations formed in said balloon, said balloon at least partially conforming to the generally cylindrical shape of said stent.	Figures 2 A and B of this application (above) depicts the approved the S8 stent delivery system with the stent crowns securely encapsulated by balloon material. The encapsulation of the stent by the balloon acts to secure the stent to the balloon. Also, see Figure 5 below depicting a cross-section of the stent on the distal end of the balloon catheter highlighting its generally cylindrical shape.

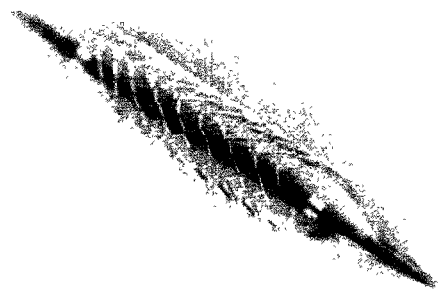
The pictures and Figures that follow correlate to the claim elements discussed in the Claim Chart on the preceding page and clearly demonstrate that Claim 1 of U.S. patent 6,309,402 (the '402 patent) reads on the S8 Over-the-Wire Coronary Stent System.

Figure 3 (below) of this application depicts the "Driver" (AKA S8Coronary stent) compressed onto catheter for delivery to an affected vessel.[3]



Note how the individual segments are aligned parallel to the balloon axis when the S8 stent is in the compressed state. Therefore, based on the analysis above the Applicant respectfully asserts that Claim 1 of United States Patent number 6,309,402 reads on the approved device, the Medtronic Vascular S8 Over-the-Wire Coronary Stent.

Figure 1 of this application showing the S8 stent balloon mounted and forcibly expanded.



In particular, claim 20 reads on a method for treating narrowing of vessels within humans using the approved device as follows:

Claim Chart Comparing Claim 20 of U.S. Patent 6,309,402 element-by-element with the method of using the S8 Over-the-Wire Coronary Stent to treat narrowing of the vessels.

Claim 20 of U.S. Patent 6,309,402	**Corresponding Features of the S8 Over-the-Wire Coronary Stent System**
20. A method of forming a stent delivery system, the method comprising:	The Medtronic Vascular DRIVER (S8 stent) Multi-Exchange Coronary Stent Delivery System having a stent mounted onto the distal end of a delivery catheter as depicted in Figures 1(expanded) and 3 (constricted) of this application.
providing a delivery catheter having a distal portion;	The S8 stent Multi-Exchange Coronary Stent Delivery System includes a balloon catheter, thus the balloon catheter is inherently "provided" in order to make the approved stent delivery system. See Figures 1(expanded) and 3 (constricted) of this application.
placing a stent on the delivery catheter distal portion whereby a portion of the delivery catheter distal portion encapsulates at least a portion of the stent; and	Figures 2 and 3 of this application show the approved device mounted on a distal balloon. Thus the stent was "placed" on the distal end of the catheter. Figure 2 A and B clearly show that a portion of the stent has been encapsulated by a portion of the catheter's distal end.
heating at least the portion of the delivery catheter distal portion encapsulating the portion of the stent.	The manufacturing process includes heating at least a portion of the delivery catheter's distal end to encapsulate a portion of the stent as depicted in Figure 2 A or B.

Figure 2 A and B (below) depicting different views of the *Secure Technology*™ endovascular device (stent) retention system. Both views show the material of a balloon catheter encapsulating the approved product (an endovascular support device AKA the S8, or Driver™ vascular stent system).

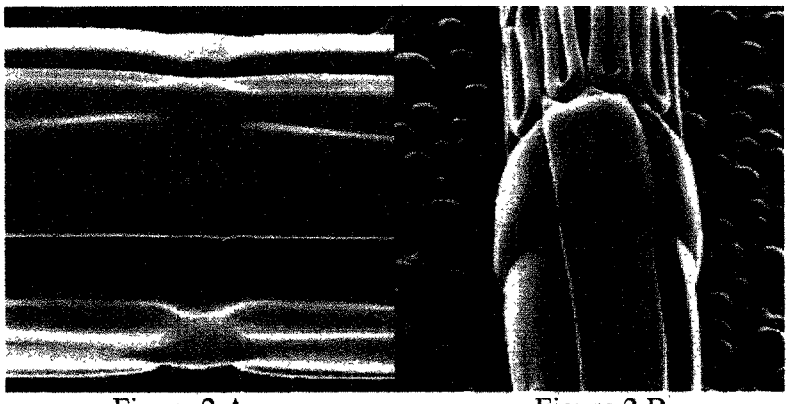


Figure 2 A Figure 2 B

Figure 4 (below) depicts at least one expanded S8 stent deployed within a previously narrowed vessel.[5]

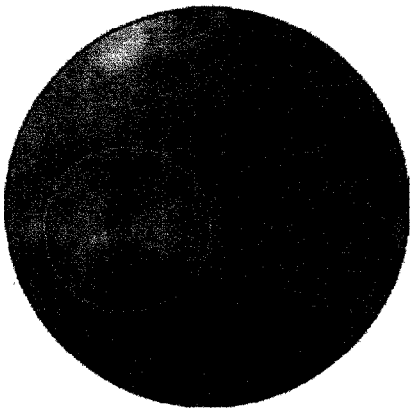


Figure 5 (below) depicts a cross-section of the approved stent delivery system clearly showing an internal lumen for selectively inflating and deflating the balloon. Note the approved S8 stent crimped around the outer circumference of the distal balloon.

New Page:

9) The relevant dates and information pursuant to 35 U.S.C. §156(g) to enable the Secretary of Health and Human Services to determine the applicable review period:

A) The effective date of the investigational device exemption (IDE) and the IDE number:

1) Conditional approval of the Applicant's IDE was dated December 20, 2001 and signed by Dr. Bram Zuckerman, Acting Director, Division of Cardiovascular and Respiratory Diseases.

2) The Applicant's IDE number is G010301, G010301/A1, A2 and A3.

B) The date on which the application for product approval under Section 515 of the Federal Food Drug and Cosmetic Act was initially submitted and the number of the application.

1) A Pre-market Approval application (PMA) for the S8 Over-the-Wire Coronary Stent System was submitted April 9, 2003.

2) The PMA number is P030009.

C) The date on which the application was approved.

The S8 Over-the-Wire Coronary Stent System PMA was approved on October 1, 2003.

New Page:

10) Brief Description of the significant activities undertaken by the marketing applicant (Medtronic Vascular) during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities.

No.	FDA Reviewer	Date	Description
G010301	Carolyn Vaughan	21-Nov-01	Original Driver Over-the-Wire Delivery System IDE Submission
G010301 / A001	Carolyn Vaughan	29-Nov-01	Submission provided on CD-ROM
G010301 / A002	Carolyn Vaughan	12-Dec-01	Histopathology/photomicrographs sent for GLP - 237
G010301 / A003	Carolyn Vaughan	14-Dec-01	List of Investigational Sites
NA	Bram Zuckerman	20-Dec-01	Conditional Approval Letter received from FDA
NA	NA	21-Dec-01	Fax sent to accounts informing them of conditional approval from FDA
G010301 / S001	Bram Zuckerman	01-Feb-02	Response to FDA Conditional Approval Letter Dated December 20, 2001
G010301 / S002	IDE Doc. Mail Ctr	05-Feb-02	Request for addition of patient guide to supply to patients
NA	NA	08-Feb-02	First patient implant for IDE Trial
G010301 / S003	IDE Doc. Mail Ctr	09-Apr-02	Report of status with ongoing animal studies
G010301 / S004	IDE Doc. Mail Ctr	11-Apr-02	Request extension to deadlines put forth in conditional approval letter
G010301 / S005	IDE Doc. Mail Ctr	22-Apr-02	Request approval for addition of 10 clinical trial sites
NA	NA	19-Apr-02	Teleconference regarding statistical questions received from the Driver conditional approval letter.
G010301 / S006	Donna-Bea Tillman	17-May-02	Response to FDA Conditional Approval Letter submitted
G010301 / S006	Donna-Bea Tillman	10-Jun-02	Approval of Driver IDE received from FDA
G010301 / S007	IDE Doc. Mail Ctr	17-Jun-02	6-Month Clinical Site Update submitted

10) Brief Description of the significant activities undertaken by the marketing applicant (Medtronic Vascular) during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities. (Continued).

No.	FDA Reviewer	Date	Description
NA	Ashley Boam	19-Aug-02	FDA determines based on new material of stent, the Driver PMA submission must be an original PMA, not a PMA supplement
G010301 / S008	IDE Doc. Mail Ctr	26-Aug-02	Report of status with ongoing animal studies
NA	NA	25-Sep-02	Last patient implant for IDE Trial
G010301 / S009	Bram Zuckerman	17-Oct-02	Report of status with ongoing animal studies
G010301 / S010	IDE Doc. Mail Ctr	23-Dec-02	Submission to FDA: Response to letter dated 11/14/2002 Final Animal Study Report (FS81)
G010301 / S011	IDE Doc. Mail Ctr	15-Jan-03	Submission response to request for additional information
G010301 / S012	IDE Doc. Mail Ctr	16-Jan-03	Annual Report Submitted
NA	Sue Bowley/ Ashley Boam	28-Feb-03	Teleconference regarding inclusion of 270-day clinical data as PMA Amendment.
P030009	PMA Doc Mail Ctr	9-Apr-03	Original FDA PMA Submission of Driver Coronary Stent Systems
P030009	Bram Zuckerman	23-May-03	FDA agreed to file PMA
P030009 / A001	PMA Doc Mail Ctr	3-Jul-03	Response submitted to FDA regarding questions from email dtd 27-May-03
P030009 / A002	PMA Doc Mail Ctr	11-Aug-03	270 day clinical data, changes to the packaging of the Over-The-Wire and Rapid Exchange delivery systems and proposed manufacturing changes to the Multi-Exchange delivery system
P030009 / A003	PMA Doc Mail Ctr	13-Aug-03	Response submitted to FDA regarding questions from email dated 12-Jul-03
P030009 / A004	PMA Doc Mail Ctr	15-Aug-03	Authorization letter for the FDA to discuss Driver PMA / STED with MHLW in Japan
P030009	Sue Bowley	19-Aug-03	Request from FDA for an additional hard copy of PMA Amendment which included 270d clinical data.
P030009 / A005	PMA Doc Mail Ctr	21-Aug-03	To notify FDA of findings from an internal audit performed by the Atlanta Cardiovascular Research Institute (ACRI) related to animal study FS70

10) Brief Description of the significant activities undertaken by the marketing applicant (Medtronic Vascular) during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities. (Continued)

No.	FDA Reviewer	Date	Description
NA	Sue Bowley/ Steve Hilbert	21-Aug-03	Samples of the OTW delivery system provided to reviewers at the request of FDA.
NA	NA	21-Aug-03	STED Desk Copies submitted to FDA
P030009	Ashley Boam	22-Aug-03	FDA confirmed with MHLW permission for cooperative review of STED
P030009 / A006	PMA Doc Mail Ctr	5-Sep-03	Request the withdrawal of Nutek Corp, located in Hayward, CA, from our list of sterilization facilities for the Driver coronary stent systems
NA	Sue Bowley/ Ashley Boam	14-Sep-03	Conclusion reached regarding format of compliance chart
P030009	Ashley Boam	22-Sep-03	Agreement with FDA to include claim for direct stenting in IFU
P030009 / A007	PMA Doc Mail Ctr	22-Sep-03	Response submitted to FDA regarding questions from email dated 17-Sep-03
P030009	Sue Bowley	25-Sep-03	90-day Status e-mail received
P030009 / A008	PMA Doc Mail Ctr	29-Sep-03	Response to FDA questions on final labeling, biomaterials compendium and conditions of approval letter
P030003	Bram Zuckerman	1-Oct-03	Driver PMA Approval received from FDA
P030009 / A009	PMA Doc Mail Ctr	8-Oct-03	Final Labeling

New Page:

11) Statement that in the opinion of the applicant that the patent is eligible for extension and a statement as to the length of extension claimed, including how the extension was calculated.

The applicant respectfully asserts that United States Patent Number 6,309,402 is eligible for extension. The applicant has demonstrated that at least one claim of U.S. Patent 6,309,402 reads on the approved device (S8 Over-the-Wire Coronary Stent) and that this application for extension is being timely filed.

The applicant respectfully asserts that U.S. Patent 6,309,402 is eligible for a 413 day extension as calculated pursuant to 37 CFR §1.777.

Calculations Under 37 CFR §1.777

1. Calculations under 37 CFR §1.777 (c)(1)

Determine the number of days in the period beginning on the date a clinical investigation on humans involving the device began and ending the date the PMA was initially submitted.

i) Clinical investigations on humans are deemed to have begun on the date that the FDA determines that an IDE required under section 520(g) of the FDCA (21 U.S.C. 360j (g) is substantially complete. In this case the records indicated that on December 20, 2001 the Medtronic Vascular IDE number G010301, G010301/A1, A2 and A3 received a Conditional Approval. Thus, this date will be used for the initial calculations .

ii) The PMA was initially filed April 9, 2003.

iii) The experimental period is thus calculated as the time between December 20, 2001 and April 9, 2003, or **476 days.**

2. Calculations under37 CFR §1.777 (c)(2)

Determine the number of days in the period beginning on the date the PMA was initially filed and ending on the date the PMA was approved.

The PMA was initially submitted April 9, 2003 and was approved October 1, 2003. Thus the approval period was **175 days**.

The Sum of 37 CFR §1.777 c(1) and 37 CFR §1.777 (c)(2) equals 651 days.

3. Calculations under 37 CFR §1.777 (d)(1)

i) Subtract the number of days in the periods (c)(1) and (c)2 of this section which were on and before the date the patent issued.

Zero days in period (c)(1) for U.S. Patent 6,309,402.

ii) Subtract the number of days in the periods (c)(1) and (c)2 of this section during which the applicant did not act with due diligence.

Zero for U.S. Patent 6,309,402.

iii) Subtract one-half the number of days remaining in the period defined by (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1)(i) and (ii).

238 days for U.S. Patent 6,309,402.

Therefore, the maximum extension available for U.S. patent number 6,309,402 For U.S. is **476 (from step 3 (i)) + 175 (from step 2) – 238 (from step 3 (iii)) = 413 days**.

4. Calculations Under 37 CFR §1.777 (d)(2)

Determine the number of days shortened by a terminal disclaimer.

Zero for the '402 patent.

Note: Although a terminal disclaimer was filed at the close of prosecution in the present case, the term of the original patent was not shortened as a result. The applicant was required to surrendered by terminal disclaimer that portion of the '402 patent that exceed the term of USPN 5,836,965 (the '965 patent). However, because the '965 patent was filed before June 8th, 1995 without a subsequent Continuing Patent Application (CPA) being filed, the term of the '965 patent is 17 years from its issue date, November 17, 1998. This results in the '965 patent expiring on November 17, 2015. However, the '402 patent was filed after June 8th, 1995 and depended from an application filed October 19, 1994 (the priority application). Thus, under 35 U.S.C. §154(a)(2) the term of the '402 patent is 20 years form October 19, 1994. Thus the expiration date is October 19, 2014 plus 60 days as calculated under 35 U.S.C. §154 (b). Therefore, the expiration date of the '402 patent, without taking into consideration the terminal disclaimer, is December 17th, 2014 which is before the expiration date of the '965 patent.

5. Calculations Under 37 CFR §1.777 (d)(3)

Section (d)3 requires that 14 years be added to the date the PMA was approved, this equals the longest possible extension available (14 years from the approval date) in this case the 37 CFR §1.777 (d)(3) date is October 1, 2017).

6. Calculations Under 37 CFR §1.777 (d)(4)

The new expiration date would be February 5, 2016 which is before October 1, 2017. However, because the '402 patent is subject to a terminal disclaimer the patent term cannot exceed November 17, 2015 (the expiration date of the '965 patent). Thus the new expiration date of the '402 patent will be November 17, 2015. Therefore, United States Patent 6,309,402 is only entitled to a 333 day extension.

7. Calculations Under 37 CFR §1.777 (d)(5)

United States Patent number 6,309,402 was filed after September 24, 1984.

12) Statement that the applicant acknowledges a duty to disclose to the Commissioner of Patents and trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

The applicant acknowledges his duty to disclose to the Commissioner of Patents and trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought. The applicant has no disclosures to that are material to the determination of entitlement to the extension sought.

13) The prescribed fee for receiving and acting upon the application for extension.

The Commissioner is hereby authorized to charge payment of the patent term extension application fee pursuant to 37 C.F.R. §1.20 (j)(1) in the amount of $1,120.00 to Deposit Account number 01-2525.

14) The name address and telephone number of the person to whom inquires and correspondences relating to the application for patent term extension are to be directed.

Michael J. Jaro, Esq.
Chief Patent Counsel
Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403

(707) 566-1746

Respectfully submitted on behalf of the applicant,

Louis C. Cullman, Esq.
USPTO Reg. No. 39,645
Stradling Yocca Carlson & Rauth